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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/991,283

11/13/2001

Elliott Farber

14358-316

3855

24633

7590

03/26/2003

HOGAN & HARTSON LLP
IP GROUP, COLUMBIA SQUARE
555 THIRTEENTH STREET, N.W.
WASHINGTON, DC 20004

EXAMINER

SHARAREH, SHAHNAM J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/991,283

Applicant(s)

FARBER, ELLIOTT

Examiner

Shahnam Sharareh

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-173 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-173 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Claims 1-173, in this application are drawn in Markush format, and contain multiple independent and patentably distinct invention. Accordingly, a requirement to provisionally elect a single independent and patentably distinct species is made as provided in MPEP § 803.02.

This application contains the following patentably distinct species directed to various methods of treating an inflammatory condition utilizing patentably distinct allantoin containing compositions having:

- I. Various emulsifying systems selected from the group
 - a) Acidic wax such as beeswax and anionic emulsifiers (claims 1-21) classified in class 514, subclass 942 or class 424, subclass 70.22.
 - b) non-ionic emulsifiers (claims 22-34) classified in class 514, subclass 943.
 - c) acidic anionic polymers and polyethylene glycol esters of stearic acid (claims 35-48), classified in class 514, subclass 943.
 - d) acidic anionic polymers and anionic emulsifiers (claims 49-59), classified in class 514, subclass 937.
 - e) acidic anionic polymers and non-ionic emulsifiers (claims 60-70) classified in class 424, subclass 401 or 70.31.
 - f) acidic anionic polymers (claims 71-83).

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- g) cetyl alcohol and stearic acid (claims 84-96), classified in class 514, subclass 938.
- h) sodium stearyl lactate and sodium isostearyl lactylate (claims 96-109) classified in class 424, subclass 400.
- i) polyethylene glycol ethers and cetearyl alcohol ethers (claims 110-122) classified in class 514, subclass 846 or 847.
- j) polyethylene glycol esters of stearic acid and glyceryl stearate (claims 123-137, 151-158), classified in class 514, subclass 860 or 865.
- k) carbohydrate polymers, acidic wax, and anionic emulsifier (claims 137-150, 159-173), classified in class 514, subclass 54+.

II. Various therapeutic agents (claims 1-173)

III. Various skin conditions (claims 1-173).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 22, 35, 49, 71, 84, 110, 123, 137 are generic.

It is considered that a Markush-type claim encompassing such species is directed to multiple independent and patentably distinct inventions since the species are so unrelated and diverse that a reference anticipating one of the species would not

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anticipate or render obvious the other species. Further, the species are considered to be independent since they are unrelated in operation, one does not require the other for ultimate use, and specification does not disclose a dependent relationship between them. Moreover, each of the stated species is considered to be patentably distinct from the others on the basis of its properties. Thus, the stated species are capable of supporting separate patents under 35 U.S.C. 121.

In the event that the Markush-type claims are not found to be allowable, the examination of the claims presented will be limited to the Markush-type claims to the extent that they read on the elected species and claims directed solely to the elected species. The claims directed solely to the non-elected species will be held withdrawn from consideration. A requirement to elect a species has been held to a tantamount to a requirement for restriction under 35 U.S.C. 121.

By species is meant a single compound. The compound may be named in any of four ways (or any combination thereof): (a) according to the IUPAC standard, (b) by a pictorial representation of the compound, (c) by setting forth the specific chemical group that each variable of the Markush group represents, or (d) by naming a claim or an example which itself sets forth a single compound.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

Ss, March 24, 2003


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200